amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with §405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) Applicability. Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in §413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(b) Methodology. Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) Multiple-source drugs. For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998]

§ 405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) General rule. A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at §414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at §414.56 of this chapter.

(b) Requirements. Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with § 424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) Civil money penalties. Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty not to exceed \$2,000 for each bill or request for payment.

[63 FR 58905, Nov. 2, 1998]

§ 405.534 Limitation on payment for screening mammography services.

(a) Basis and scope. This section implements section 1834(c) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth

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in paragraphs (b) through (d) of this section.

- (b) Global or complete service billing representing both the professional and technical components of the procedure. If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:
 - (1) The actual charge for the service.
- (2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.
- (3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is \$59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.
- (c) Professional component billing representing only the physician's interpretation for the procedure. If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:
- (1) The actual charge for the professional component of the service.
- (2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.
- (3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.
- (d) Technical component billing representing other resources involved in furnishing the procedure. If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:
- (1) The actual charge for the technical component of the service.
- (2) The amount established for the technical component of a diagnostic bi-

lateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994]

§ 405.535 Special rules for nonparticipating physicians and suppliers furnishing screening mammography services

If screening mammography services are furnished to a beneficiary by a non-participating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in §405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at §414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997]

Subpart F—[Reserved]

Subpart G—Reconsiderations and Appeals Under Medicare Part A

AUTHORITY: Secs. 1102, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c-4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

Source: $37\ FR\ 5814,\ Mar.\ 22,\ 1972,\ unless$ otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.701 Basis, purpose and definitions.

(a) This subpart implements section 1869 of the Social Security Act. Section 1869(a) provides that the Secretary will make determinations about the following matters, and section 1869(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to: